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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,386

03/19/2004

Michael L. Garrison

1-37234

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11/30/2006

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,386

Applicant(s)

GARRISON ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 15-17, 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-14 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This action is in response to applicants' amendment filed 6 October 2006. The amendment has been considered, however, it does not place the application in condition for allowance. The examiner acknowledges the corrections made to the abstract, specification, and claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by **Kirkman** (U.S. Patent No. **6,071,263**).

Claim 1: Kirkman discloses a method for delivering and deploying an expandable intraluminal device, providing a delivery system comprising an elongate member **4** having proximal and distal ends, and the expandable intraluminal medical device **154** circumferentially disposed about a portion of the elongate member **4** (Figure 10A and 10B). The distal end of the elongate member **4** is inserted into a body vessel, and the distal end of the elongate member **4** is advanced **4** through the body vessel to the desired point of treatment. A portion of the elongate member is spaced from a wall surface of the blood vessel, and the expandable intraluminal medical device is deployed

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from the elongate member. Lastly, the elongate member is withdrawn from the body vessel (col. 12, lines 26-28 and col. 13, lines 5-50).

Claim 2: Kirkman also discloses that the step of spacing a portion of the elongate member from a wall surface of the body vessel comprises spacing a portion of the elongate member that includes the expandable intraluminal device **154**, which lies at the catheter tip **8** (col. 12, lines 55-59).

Claim 3: Kirkman discloses that the elongate member **2** defines a lumen and the delivery system further comprises an ancillary delivery device **9** having a means for spacing a portion of the elongate member **2** from a wall surface of a body vessel (col. 3, lines 50-53 and col. 6, lines 43-47).

Claim 4: Kirkman discloses the means for spacing comprising a basket **9** formed from four wires **12** and having expanded and collapsed configurations (Figures 2A-2B and col. 8, lines 15-19).

Claim 13: Kirkman discloses a delivery system comprising an elongate member **4** having proximal and distal ends and defining a first lumen, an expandable intraluminal medical device **154** circumferentially disposed about a portion of the elongate member (Figure 10A and 10B), a sheath circumferentially disposed about the elongate member and the expandable intraluminal device, the sheath being movable along the elongate member (col. 8, lines 3-19), and an ancillary delivery device **9** disposed in the first lumen and having a basket formed from at least two wire members **156**, **158**, **160** and having expanded and collapsed configurations, wherein the basket is in the collapsed configuration when disposed in the first lumen and is in the expanded configuration

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when not disposed in the first lumen (col. 3, lines 50-53 and col. 6, lines 43-37, and col. 13, lines 5-50).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kirkman** (U.S. Patent No. **6,071,263**) in view of **St. Germain et al.** (U.S. Patent No **5,534,007**).

Claim 8: Kirkman discloses the claimed steps except for the delivery system further comprising a sheath that is circumferentially disposed about the elongate member and movable along the elongate member, and wherein the step of deploying the expandable intraluminal device comprises retracting the sheath from a position about the expandable intraluminal medical device

St. Germain et al. teaches deployment catheter for an expandable intraluminal device that comprises a sheath **40** that is circumferentially disposed about and movable along an elongate member **5**, and the step of deploying the expandable intraluminal device **35** comprises retracting the sheath **40** from a position about the expandable intraluminal medical device **35** (Figure 1 and col. 3, lines 27-36). St. Germain et al. teaches that the use of the sheath **40** retains the expandable intraluminal device **35** and

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protects the vessel wall (col. 3, lines 36-38). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a sheath that is circumferentially disposed about the elongate member and retracting the sheath in the step of deploying the expandable intraluminal device, as taught by St. Germain et al., to Kirkman in order to retain the expandable intraluminal device before deployment and to protect the vessel wall from injury.

Claim 9: Kirkman discloses the elongate member **2** defining a lumen and the delivery system further comprising an ancillary delivery device **9** disposed within the lumen, the ancillary delivery device having a means for spacing a portion of the elongate member from a wall surface of a body vessel (Figures 2A and 2B).

Claims 10-11: Kirkman discloses the step of spacing a portion of the elongate member from a wall surface of the body vessel which comprises activating the means for spacing, which includes retracting the sheath from a position about the means for spacing (col. 8, lines 10-19).

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kirkman** (U.S. Patent No. **6,071,263**) in view of **Pavcnik et al.** (U.S. Pub. No. **20010039450**).

Claim 12: Kirkman discloses the claimed steps except for the expandable intraluminal medical device comprising a prosthetic venous valve

Pavcnik et al. teaches an intraluminal venous valve **43** that is deployed within the blood vessel and exerts force against the wall of the vessel and provides a partial seal

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against the wall, while having expandable and collapsible features (Figures 48-49 and page 1, paragraph 6, page 6, paragraph 68, and page 10, paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a prosthetic venous valve device, as taught by Pavcnik et al., to the device of Kirkman, since it was known in the art that the delivery system may deploy any suitable expandable intraluminal medical device, such as a prosthetic venous valve.

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kirkman** (U.S. Patent No. **6,071,263**), as applied to Claim 13 above, and further in view of **Pavcnik et al.** (U.S. Pub. No. **20010039450**).

Claim 18: Kirkman discloses the claimed device except for the expandable intraluminal device comprising a prosthetic venous valve.

Pavcnik et al. teaches an intraluminal venous valve **43** that is deployed within the blood vessel and exerts a force against the wall of the vessel and provides a partial seal against the wall, while having expandable and collapsible features (Figures 48-49 and page 1, paragraph 6 and page 6, paragraph 68, and page 10, paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a prosthetic venous valve device, as taught by Pavcnik et al., to the device of Kirkman, since it was known in the art that the delivery system may deploy any suitable expandable intraluminal medical device, such as a prosthetic venous valve.

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7. Claim 14 is U.S.C. 103(a) as being unpatentable over **Kirkman** (U.S. Patent No. **6,071,263**), as applied to Claim 13 above, and in further view of **Levine et al.** (U.S. Pub. No. **20040087965**).

Claim 14: Kirkman discloses the claimed device except for the at least two wire members comprising flat wire.

Levine et al. teaches wire members **104** comprising flat wire (page 3, paragraph 37). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Kirkman by using flat wire, as taught by Levine et al. since it was known in the art that flat wire would provide more surface area and therefore better contact or engagement with surfaces.

Response to Arguments

8. Applicant's arguments filed 6 October 2006 have been fully considered but they are not persuasive.

9. Applicant argues that Kirkman does not disclose the steps of "spacing a portion of the elongate member from a wall surface of the body vessel" and "deploying said expandable intraluminal medical device from the elongate member" as separate steps and that Kirkman is incapable of performing these steps separately. However, the claim does not recite steps being executed "separately," and therefore the device and method of Kirkman reads on the limitations set forth in Claims 1 through 4, as mentioned above.

10. Applicant argues that St. Germain does not cure the defect of Kirkman in disclosing a sheath that is circumferentially disposed about the elongate member and

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has failed to establish a prima facie case of obviousness. The examiner disagrees. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Kirkman in view of St. Germain reads on the limitations recited in Claims 8 through 11, as maintained above.

11. Applicant argues that Pavcnik does not cure the defect of Kirkman in teaching a an expandable intraluminal device comprising a prosthetic venous valve and has failed to establish a prima facie case of obviousness. The examiner disagrees. Kirkman in view of Pavcnik et al. reads on the limitations recited in Claim 12, as maintained above.

12. Applicant's arguments with respect to Claims 13, 14, and 18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, reading "Michael J. Hayes". The signature is fluid and cursive, with the first name "Michael" and last name "Hayes" clearly distinguishable.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER